Inspectional Efforts to Achieve SUD Reprocessor Compliance

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Historically

- Since early 1990's third party reprocessors have been inspected for compliance with FDA's device manufacturing requirements
- FDA has inspected most, if not all, third party reprocessors known to the agency
- FDA has visited over 3 dozen hospitals since November 2001

Historically *(continued)*

- Frequency of reprocessor inspections has increased in recent years due to FDA's new enforcement strategy

Third Party Reprocessor Inspections since 1998

- FDA has identified 15 third party reprocessors, some having more than 1 facility
- No legal actions have been taken, however,
- 11 have received warning letters, some receiving more than 1

Checking a Firm's Compliance

- Warning Letters issued by FDA can be accessed on the agency's homepage

  www.fda.gov/foi/warning.htm

  - Select search by firm name
  - Select first letter of firm name*

*Note the timeframe in the heading. Search should also include archived letters.

Checking for Compliance
(continued)

- Were deficiencies in Warning Letter corrected?
- The answer should be in a subsequent inspection report. Reports and 483s are available from:

Checking for Compliance
(continued)

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As of July 2002

- 2 hospitals were found reprocessing SUDs without meeting FDA requirements (Registration/Listing & Premarket)
- 1 hospital received a Warning Letter;
- 2nd hospital received an Untitled Letter
- No legal actions have been taken

Beginning August 14, 2002

- Hospitals reprocessing SUDs will be expected to comply with all FDA regulations applicable to medical device manufacturers

Overview of Regulations Available

- CD Rom: *An Overview of the Regulatory Requirements for Reprocessing of Single-Use Devices by Hospitals*
  - Request a free copy at:

http://www.fda.gov/cdrh/reuse/reuse-important.shtml